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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,441	05/03/2005	Tomoji Maruyama	260364US90PCT	9474
22850	7590	05/08/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER YABUT, DIANE D	
			ART UNIT	PAPER NUMBER
			3734	
			NOTIFICATION DATE	DELIVERY MODE
			05/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/511,441	Applicant(s) MARUYAMA ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/24/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8,25-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 02/24/2009.

Claims 2-31 are pending in the application. Claims 9-24 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 2-4, 7-8, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by **Gordon** (U.S. Patent No. **5,364,408**).

Claim 2: Gordon discloses a body part (distal end of **2**), with a predetermined length, having a rotary portion (near **14**) and can be inserted into said tissue of said organism from a hole formed subcutaneously in a tissue membrane of an organism, two hollow needle members **10** accommodated in a portion, inside said body part, rearward from said rotary portion, a needle member operation portion (proximal of **10**) for advancing said two hollow needle members toward said rotary portion from a side surface of said body part (Figures 1B-1D), and two openings disposed at a rear portion of said body part (proximal end of needles **10**) and communicating with an inside of said two hollow needle members, wherein said rotary portion has two needle member receiving portions for receiving a distal end of one of said hollow needle members and that of the other of

Art Unit: 3734

said hollow needle members **10** respectively pressed out of said body part, and a connection duct (where suturing thread **4** is accumulated near **12**) communication with said two needle member receiving portions, and a duct for a suturing thread **4** is formed in a range from one of said two openings to the other of said openings through an inside of one of said two hollow needle members, said connection duct, and an inside of the other of said two hollow needle members, when said two needle member receiving portions receive said hollow needle members respectively at a same time (Figure 1A).

Claims 3-4 and 7-8: Gordon discloses a suturing member which can be inserted into said duct for a suturing thread, and said suturing member includes a guide portion linearly formed of an elastic material and a suturing thread portion provided on said guide portion and the rotary portion has a thread pull-out slit extending from an upper surface thereof and communicating with said two needle member receiving portions and said connection duct (Figure 1A), an urging member for urging said needle member operation portion or said hollow needle member rearward and a stopper configured to stop said hollow needle members at a position pressed by said needle member operation portion, and an opening is formed at a rear end of said needle member operation portion (Figures 1B-1H).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 25-26 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gordon** (U.S. Patent No. **5,364,408**).

Claims 25-26: Gordon discloses the claimed organism tissue suturing apparatus, as described above, which encompasses the same invention as the method steps including rotating the rotary portion in the tissue until the body part becomes oblique at a predetermined angle with respect to an axis of the rotary portion, returning the first hollow needle member and the second hollow needle member into the body part, returning the rotary portion to an initial position, and pulling out the organism tissue suturing apparatus out of the puncture site and leaving the suture thread (Figures 1A-1H), except for using the organism tissue suturing apparatus in a penetrated hole formed in a blood vessel. It would have been obvious to one of ordinary skill in the art at the time of invention to utilize the tissue suturing apparatus in a blood vessel, since Gordon discloses a method and device for approximating tissue, and it was well known in the art to occlude or approximate tissue in a vascular lumen or blood vessel to effectively suture a puncture or hole.

Claim 31: Although Gordon discloses the two openings exit at the rear-most portion of the organism tissue suturing apparatus, they may not necessarily be located at an

“extreme-most portion” of the needle member operation portion. However, since applicant has not disclosed that having the openings at an extreme-most portion of the needle member operation portion solves any stated problem or is for any particular purpose (applicant discloses in specification paragraph 84 that the two openings are “preferably” at the rear end of the device) and it appears that the invention would perform equally well with the two openings located at an extreme-most portion.

5. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gordon** (U.S. Patent No. **5,364,408**), as applied to Claim 2 above, and further in view of **Kortenbach** (U.S. Patent No. **6,096,051**).

Claims 5-6: Gordon discloses the claimed device except for a rotary portion towing wire which extends inside said body part and is fixed to said rotary portion at one end thereof, wherein said body part has a supporting pin for rotatably supporting said rotary portion, and said rotary portion having a side-surface opening, for receiving said supporting pin, formed long and axially extending to allow sliding of said supporting pin, a rotation angle restriction function permitting a rotation of said rotary portion between a state in which said rotary portion is on an approximate extension line of an axis of said body part and a predetermined angle less than 90 degrees.

Kortenbach teaches a rotary portion towing wire which extends inside said body part and is fixed to said rotary portion at one end thereof, wherein said body part has a supporting pin for rotatably supporting said rotary portion, and said rotary portion having

Art Unit: 3734

a side-surface opening, for receiving said supporting pin, formed long and axially extending to allow sliding of said supporting pin, and a rotation angle restriction function permitting a rotation of said rotary portion between a state in which said rotary portion is on an approximate extension line of an axis of said body part and a predetermined angle less than 90 degrees (Figures 6D-6F). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotary portion towing wire and pin and a rotation angle restriction function, as taught by Kortenbach, to Gordon, since it was known in the art that the rotary portions commonly have pins for hinges to allow for secure rotation as well as rotation restriction functions to avoid undesirable movement of the apparatus that may injure tissue.

Response to Arguments

6. Applicant's arguments filed 02/24/2009 have been fully considered but they are not persuasive.
7. The applicant argues that Gordon fails to teach a continuous duct for a suturing thread formed in the range from one of said two openings to the other of said openings through one of said lumens of one of said two hollow needle members, said connection duct of said rotary portion, and the other of said lumens of the other of said two hollow needle members, when said two needle member receiving portions receive said hollow needle members respectively at the same time. The applicant indicates that there is a gap formed between the ends of the two needles which exposes the suturing thread as

seen in Figures 4A. In the Interview Summary dated 02/12/2009, the examiner indicated that the arguments appeared to read over the prior art of record.

8. However, upon further consideration, it is evident that a continuous duct or pathway is created in Gordon ranging from the proximal opening of one needle **10** to a connection duct **12** to the other proximal opening of the opposite needle **10** (see Figure 1A) in that the needles **10** and the connection duct **12** are in immediate and direct fluid communication with each other, or have paths which overlap, and provide a pathway through which suture **4** is contained. The suture may be exposed outside of the needles **10**, yet it is still contained and enclosed within the duct created by the needles **10** and the connection duct **12** in the condition where the needles **10** are contained within the suturing device body portion. In this sense, the needles and the suturing device body (which contain the needles) in the device of Gordon therefore create a “continuous duct” or pathway through which an element (suture) is enclosed.

9. Applicant also argues that the two openings of the needle members are not disposed at a rear-most portion, but rather in a middle portion of the device. As maintained above, since applicant has not disclosed that having the openings at a rear-most or extreme-most portion of the needle member operation portion solves any stated problem or is for any particular purpose (applicant discloses in specification paragraph 84 that the two openings are “preferably” at the rear end of the device) and it appears that the invention would perform equally well with the two openings located at a rear-most or extreme-most portion.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734